UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/590,539	05/30/2007	Peter David East	76786/JPW/CH	9795

23432 7590 10/10/2008

COOPER & DUNHAM, LLP
1185 AVENUE OF THE AMERICAS
NEW YORK, NY 10036

EXAMINER	
GANGLE, BRIAN J	

ART UNIT	PAPER NUMBER
1645	

MAIL DATE	DELIVERY MODE
10/10/2008	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/590,539	EAST ET AL.	
	Examiner	Art Unit	
	Brian J. Gangle	1645	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *27 June 2008*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1,5,6,8-18,20,21,23,25 and 27* is/are pending in the application.

4a) Of the above claim(s) *1,5,11,12,14,16-18,20,21,23,25 and 27* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *6,8-10,13 and 15* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☒ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *24 August 2006* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☒ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *8/24/06,6/1/07,7/21/08*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Election/Restrictions

Applicant's election with traverse of Group V and SEQ ID NO:4 in the reply filed on 6/27/2008 is acknowledged. The traversal is on the following ground(s): That the polypeptide disclosed by Schuhmann (and used by the examiner to break unity) is known in the art as a defensin. Applicant asserts that defensins are completely structurally distinct from the moricins of the claimed invention. Applicant asserts that, at the amino acid level, the defensins of Schuhmann and the instant invention are unrelated and points out a very low level of homology between the two. Applicant also asserts that, although the claims refer to biologically active fragments, there is no justification to consider that this "does not provide a special technical feature over Schuhmann" and that issues related to the inventiveness and novelty of the claimed fragments are more appropriately dealt with during substantive examination. Finally, applicant asserts that the claims are clearly linked by a single general inventive concept and should all be examined.

Upon reconsideration, Group II is rejoined with Group V.

With regard to the restriction of the other groups, applicant's arguments have been fully considered and deemed non-persuasive.

Regardless of what the various proteins claimed by applicant are called in the art, the invention is defined by the words used in the claims. Despite applicant's assertion, the proteins disclosed by Schuhmann and shown in the instant claims are not "completely structurally distinct"; in fact, they share amino acid sequences, which is all that is required by the claims. The examiner is not making reference to "biologically active fragments"; therefore, this line of argument is not relevant. The general inventive concept that links the claims is defined by those claims; in this case, Schuhmann discloses proteins that meet the limitations of the claims and thus there is no special technical feature linking the claims.

The requirement is still deemed proper and is therefore made FINAL.

As stated above, Group II is rejoined with Group V. Claims 1, 5-6, 8-18, 20-21, 23, 25, and 27 are pending. Claims 1, 5, 11-12, 14, 16-18, and 20-21, 23, 25, and 27 are withdrawn as being drawn to nonelected inventions. Claims 6, 8-10, 13, and 15 are currently under examination.

Priority

Receipt is acknowledged of papers submitted under 35 U.S.C. 119(a)-(d), which papers have been placed of record in the file.

Information Disclosure Statement

The information disclosure statements filed on 8/24/2006, 6/1/2007, and 7/21/2008 have been considered. Initialed copies are enclosed.

Specification

The use of the trademark FICOLL has been noted in this application on page 19. It should be capitalized wherever it appears and be accompanied by the generic terminology.

Although the use of trademarks is permissible in patent applications, the proprietary nature of the marks should be respected and every effort made to prevent their use in any manner which might adversely affect their validity as trademarks.

It is noted that the cited occurrence of improper use is only exemplary and applicant should review the specification to correct any other use of trademarks.

Claim Objections

Claim 6 is objected to because it depends from a nonelected claim. Appropriate correction is required.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claim 15 is rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

Applicant is directed to the Guidelines for the Examination of Patent Applications Under the 35 U.S.C. 112, first paragraph "Written Description" Requirement, Federal Register, Vol. 66, No. 4, pages 1099-1111, Friday January 5, 2001.

The instant claims are drawn to a transgenic plant that has been transformed with a polynucleotide that comprises a sequence of nucleotides provided in SEQ ID NO:9, a sequence of nucleotides which is at least 66% identical to SEQ ID NO:9, or a sequence that hybridizes to either of these under high stringency conditions. Said transgenic plant must produce a peptide with an amino acid sequence as provided in SEQ ID NO:4, an amino acid sequence which is at least 60% identical to SEQ ID NO:4, a biologically active fragment of these, or a precursor comprising these sequences. Said peptide must exhibit antifungal and/or antibacterial activity.

The specification discloses SEQ ID NO:9, which is cDNA encoding pre-Gm-moricinA (SEQ ID NO:1) and SEQ ID NO:4, which is Gm-moricinA, an antimicrobial peptide produced by *Galleria mellonella*. However, the claim encompasses proteins with only 60% sequence homology to SEQ ID NO:4, as well as nucleotides that hybridize to any portion SEQ ID NO:9, and any amino acid sequence found in SEQ ID NO:4 (which includes any two amino acids). These peptides have no correlation between their structure and function. The claim requires that the peptide exhibit antifungal and/or antibacterial activity, but the specification provides no guidance regarding which variants or fragments are capable of the required function. Therefore,

the specification provides insufficient written description to support the genus encompassed by the claim. Vas-Cath Inc. v. Mahurkar, 19 USPQ2d 1111, makes clear that

"applicant must convey with reasonable clarity to those skilled in the art that, as of the filing date sought, he or she was in possession of the invention. The invention is, for purposes of the 'written description' inquiry, whatever is now claimed." (See page 1117.) The specification does not "clearly allow persons of ordinary skill in the art to recognize that [he or she] invented what is claimed." (See Vas-Cath at page 1116.)

With the exception of SEQ ID NO:1, 4, and 9, the skilled artisan cannot envision the detailed chemical structure of the encompassed polypeptides, regardless of the complexity or simplicity of the method of isolation. Adequate written description requires more than a mere statement that it is part of the invention and reference to a potential method for isolating it. The nucleic acid and/or protein itself is required. See Fiers v. Revel, 25 USPQ2d 1601, 1606 (CAFC 1993) and Amgen Inc. V. Chugai Pharmaceutical Co. Ltd., 18 USPQ2d 1016. In Fiddes v. Baird, 30 USPQ2d 1481, 1483, claims directed to mammalian FGF's were found unpatentable due to lack of written description for the broad class. The specification provided only the bovine sequence.

University of California v. Eli Lilly and Co., 43 USPQ2d 1398, 1404. 1405 held that:

...To fulfill the written description requirement, a patent specification must describe an invention and does so in sufficient detail that one skilled in the art can clearly conclude that "the inventor invented the claimed invention." Lockwood v. American Airlines Inc. , 107 F.3d 1565, 1572, 41 USPQ2d 1961, 1966 (1997); In re Gosteli , 872 F.2d 1008, 1012, 10 USPQ2d 1614, 1618 (Fed. Cir. 1989) (" [T]he description must clearly allow persons of ordinary skill in the art to recognize that [the inventor] invented what is claimed."). Thus, an applicant complies with the written description requirement "by describing the invention, with all its claimed limitations, not that which makes it obvious," and by using "such descriptive means as words, structures, figures, diagrams, formulas, etc., that set forth the claimed invention." Lockwood, 107 F.3d at 1572, 41 USPQ2datl966.

Protein chemistry is probably one of the most unpredictable areas of biotechnology. Consequently, the effects of sequence dissimilarities upon protein structure and function cannot be predicted. Bowie *et al.* (Science, 1990, 247:1306-1310) teach that an amino acid sequence encodes a message that determines the

shape and function of a protein and that it is the ability of these proteins to fold into unique three-dimensional structures that allows them to function and carry out the instructions of the genome and further teaches that the problem of predicting protein structure from sequence data and in turn utilizing predicted structural determinations to ascertain functional aspects of the protein is extremely complex (column 1, page 1306). Bowie *et al.* further teach that while it is known that many amino acid substitutions are possible in any given protein, the position within the protein's sequence where such amino acid substitutions can be made with a reasonable expectation of maintaining function are limited. Certain positions in the sequence are critical to the three dimensional structure/function relationship and these regions can tolerate only conservative substitutions or no substitutions at all (column 2, page 1306). The sensitivity of proteins to alterations of even a single amino acid in a sequence are exemplified by Burgess *et al.* (J. Cell Biol. 111:2129-2138, 1990) who teach that replacement of a single lysine reside at position 118 of acidic fibroblast growth factor by glutamic acid led to the substantial loss of heparin binding, receptor binding and biological activity of the protein and by Lazar *et al.* (Mol. Cell. Biol., 8:1247-1252, 1988) who teach that in transforming growth factor alpha, replacement of aspartic acid at position 47 with alanine or asparagine did not affect biological activity while replacement with serine or glutamic acid sharply reduced the biological activity of the mitogen. These references demonstrate that even a single amino acid substitution will often dramatically affect the biological activity and characteristics of a protein. Additionally, Bork (Genome Research, 2000,10:398-400) clearly teaches the pitfalls associated with comparative sequence analysis for predicting protein function because of the known error margins for high-throughput computational methods. Bork specifically teaches that computational sequence analysis is far from perfect, despite the fact that sequencing itself is highly automated and accurate (p. 398, column 1). One of the reasons for the inaccuracy is that the quality of data in public sequence databases is still insufficient. This is particularly true for data on protein function. Protein function is context dependent, and both molecular and cellular aspects have to be considered (p. 398, column 2). Conclusions from the comparison analysis are often stretched with

regard to protein products (p. 398, column 3). Further, although gene annotation via sequence database searches is already a routine job, even here the error rate is considerable (p. 399, column 2). Most features predicted with an accuracy of greater than 70% are of structural nature and, at best, only indirectly imply a certain functionality (see legend for table 1, page 399). As more sequences are added and as errors accumulate and propagate it becomes more difficult to infer correct function from the many possibilities revealed by database search (p. 399, paragraph bridging columns 2 and 3). The reference finally cautions that although the current methods seem to capture important features and explain general trends, 30% of those features are missing or predicted wrongly. This has to be kept in mind when processing the results further (p. 400, paragraph bridging cols 1 and 2). Given not only the teachings of Bowie *et al.*, Lazar *et al.* and Burgess *et al.* but also the limitations and pitfalls of using computational sequence analysis and the unknown effects of alternative splicing, post translational modification and cellular context on protein function as taught by Bork, the claimed proteins could not be predicted based on sequence identity to SEQ ID NO:4. Clearly, it could not be predicted that polypeptide or a variant that shares only partial homology with a disclosed protein or that is a fragment of a given SEQ ID NO. will function in a given manner (i.e. serve as an antifungal and/or antibacterial compound).

Furthermore, the specification does not describe any proteins that are encoded by a nucleic acid that is able to hybridize with SEQ ID NO:9. It is well known in the art that DNA that hybridizes to the DNA sequence that encodes a protein is known as complementary DNA. "Complementary" is routinely used in the art to describe the opposite (complement) strand of a given DNA sequence, therefore the claim reads upon a protein that is encoded by DNA that is antisense to the nucleic acid which encodes SEQ ID NO:4, or the antisense of SEQ ID NO:9. It is well known that antisense sequences do not encode products related to the sense strand, for example, the 5'- 3' directionality is reversed, and therefore each codon triplets is read in the reverse orientation (encoding a different amino acid in most instances) and the N and C terminal of the encoded product is reversed. Applicant has not provided any guidance or working examples which would lead one of skill in the art to predict that the antisense

strand of SEQ ID NO:9 (e.g. a nucleic acid which hybridizes to SEQ ID NO:9) does, in fact, encode protein product (e.g. start sequences, methionine codon, a substantial open reading frame, stop and other termination signals). Further, one of skill in the art would not predict that such a product would be structurally or functionally related to the protein with the sequence of SEQ ID NO:4, and applicant has not provided any potential means of using such an unrelated protein product, or any description of the structure or function of such a product.

Therefore, only SEQ ID NO:1, 4, and 9, but not the full breadth of the claims, meet the written description provision of 35 USC 112, first paragraph. The species specifically disclosed are not representative of the genus because the genus is highly variant. Applicant is reminded that Vas-Cath makes clear that the written description provision of 35 USC 112 is severable from its enablement provision. (See page 1115).

Claims 6, 8-10, 13, and 15 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for isolated polynucleotides comprising the sequence of SEQ ID NO:9, vectors and isolated host cells comprising said polynucleotides, and transgenic plants having been transformed with said polynucleotides which produce a polypeptide comprising SEQ ID NO:4, does not reasonably provide enablement for the full scope of the claims as drawn. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the invention commensurate in scope with these claims.

Enablement is considered in view of the Wands factors (MPEP 2164.01(A)). These include: nature of the invention, breadth of the claims, guidance of the specification, the existence of working examples, state of the art, predictability of the art and the amount of experimentation necessary.

In re Fisher, 427 F.2d 833, 839, 166 USPQ 18, 24 (CCPA 1970) states, "The amount of guidance or direction needed to enable the invention is inversely related to the amount of knowledge in the state of the art as well as the predictability in the art." "The "amount of guidance or direction" refers to that information in the application, as

originally filed, that teaches exactly how to make or use the invention. The more that is known in the prior art about the nature of the invention, how to make, and how to use the invention, and the more predictable the art is, the less information needs to be explicitly stated in the specification. In contrast, if little is known in the prior art about the nature of the invention and the art is unpredictable, the specification would need more detail as to how to make and use the invention in order to be enabling" (MPEP 2164.03). The MPEP further states that physiological activity can be considered inherently unpredictable. Thus, Applicant assumes a certain burden in establishing that inventions involving physiological activity are enabled. All of the Wands factors have been considered with regard to the instant claims, with the most relevant factors discussed below.

Nature of the invention: The instant claims are drawn to an isolated polynucleotide that comprises a sequence of nucleotides provided in SEQ ID NO:9, a sequence of nucleotides which is at least 66% identical to SEQ ID NO:9, or a sequence that hybridizes to either of these under high stringency conditions, as well as a vector comprising said polynucleotide and a host cell comprising said polynucleotide. The claims are also drawn to a transgenic plant that has been transformed with a polynucleotide that comprises a sequence of nucleotides provided in SEQ ID NO:9, a sequence of nucleotides which is at least 66% identical to SEQ ID NO:9, or a sequence that hybridizes to either of these under high stringency conditions. Said transgenic plant must produce a peptide with an amino acid sequence as provided in SEQ ID NO:4, an amino acid sequence which is at least 60% identical to SEQ ID NO:4, a biologically active fragment of these, or a precursor comprising these sequences. Said peptide must exhibit antifungal and/or antibacterial activity. While only claim 15 recites the function of antifungal and/or antibacterial activity, the only disclosed utility for the polypeptides encoded by the claimed polynucleotides is as an antifungal and/or antibacterial compound.

Breadth of the claims: The claims encompass any polynucleotide that shares two consecutive nucleotides with SEQ ID NO:9 as well as any polynucleotide that can hybridize (under undefined high stringency conditions) with any portion of SEQ ID NO:9.

Claim 9 recites "a host cell" comprising the above polynucleotide. This claim encompasses transgenic animals as well as transgenic plants. Claim 15 encompasses a transgenic plant transformed with said polynucleotide and which produces a peptide with any amino acid sequence found in SEQ ID NO:4 (including any two consecutive amino acids), as well as biologically active fragments of said peptide. The peptide must have antifungal and/or antibacterial activity.

Guidance of the specification/The existence of working examples: The specification discloses SEQ ID NO:9, which is cDNA encoding pre-Gm-moricinA (SEQ ID NO:1) and SEQ ID NO:4, which is Gm-moricinA, an antimicrobial peptide produced by *Galleria mellonella*. The specification also includes a working example where *Arabidopsis* is transformed with full length Gm-moricinA genes and one where an insect cell line (*in vitro*) is transformed.

State of the art: Protein chemistry is probably one of the most unpredictable areas of biotechnology. Consequently, the effects of sequence dissimilarities upon protein structure and function cannot be predicted. Bowie *et al.* (Science, 1990, 247:1306-1310) teach that an amino acid sequence encodes a message that determines the shape and function of a protein and that it is the ability of these proteins to fold into unique three-dimensional structures that allows them to function and carry out the instructions of the genome and further teaches that the problem of predicting protein structure from sequence data and in turn utilizing predicted structural determinations to ascertain functional aspects of the protein is extremely complex (column 1, page 1306). Bowie *et al.* further teach that while it is known that many amino acid substitutions are possible in any given protein, the position within the protein's sequence where such amino acid substitutions can be made with a reasonable expectation of maintaining function are limited. Certain positions in the sequence are critical to the three dimensional structure/function relationship and these regions can tolerate only conservative substitutions or no substitutions at all (column 2, page 1306). The sensitivity of proteins to alterations of even a single amino acid in a sequence are exemplified by Burgess *et al.* (J. Cell Biol. 111:2129-2138, 1990) who teach that replacement of a single lysine reside at position 118 of acidic fibroblast growth factor by

glutamic acid led to the substantial loss of heparin binding, receptor binding and biological activity of the protein and by Lazar *et al.* (Mol. Cell. Biol., 8:1247-1252, 1988) who teach that in transforming growth factor alpha, replacement of aspartic acid at position 47 with alanine or asparagine did not affect biological activity while replacement with serine or glutamic acid sharply reduced the biological activity of the mitogen. These references demonstrate that even a single amino acid substitution will often dramatically affect the biological activity and characteristics of a protein. Additionally, Bork (Genome Research, 2000,10:398-400) clearly teaches the pitfalls associated with comparative sequence analysis for predicting protein function because of the known error margins for high-throughput computational methods. Bork specifically teaches that computational sequence analysis is far from perfect, despite the fact that sequencing itself is highly automated and accurate (p. 398, column 1). One of the reasons for the inaccuracy is that the quality of data in public sequence databases is still insufficient. This is particularly true for data on protein function. Protein function is context dependent, and both molecular and cellular aspects have to be considered (p. 398, column 2). Conclusions from the comparison analysis are often stretched with regard to protein products (p. 398, column 3). Further, although gene annotation via sequence database searches is already a routine job, even here the error rate is considerable (p. 399, column 2). Most features predicted with an accuracy of greater than 70% are of structural nature and, at best, only indirectly imply a certain functionality (see legend for table 1, page 399). As more sequences are added and as errors accumulate and propagate it becomes more difficult to infer correct function from the many possibilities revealed by database search (p. 399, paragraph bridging columns 2 and 3). The reference finally cautions that although the current methods seem to capture important features and explain general trends, 30% of those features are missing or predicted wrongly. This has to be kept in mind when processing the results further (p. 400, paragraph bridging cols 1 and 2).

While only claim 15 recites the function of antifungal and/or antibacterial activity, the only disclosed utility for the polypeptides encoded by the claimed polynucleotides is as an antifungal and/or antibacterial compound. Given not only the teachings of Bowie

et al., Lazar *et al.* and Burgess *et al.* but also the limitations and pitfalls of using computational sequence analysis and the unknown effects of alternative splicing, post translational modification and cellular context on protein function as taught by Bork, the claimed proteins could not be predicted based on sequence identity to SEQ ID NO:4. Clearly, it could not be predicted that polypeptide or a variant that shares only partial homology with a disclosed protein or that is a fragment of a given SEQ ID NO. will function in a given manner (i.e. serve as an antifungal and/or antibacterial compound).

Furthermore, the specification does not describe any proteins that are encoded by a nucleic acid that is able to hybridize with SEQ ID NO:9. It is well known in the art that DNA that hybridizes to the DNA sequence that encodes a protein is known as complementary DNA. "Complementary" is routinely used in the art to describe the opposite (complement) strand of a given DNA sequence, therefore the claim reads upon a protein that is encoded by DNA that is antisense to the nucleic acid which encodes SEQ ID NO:4, or the antisense of SEQ ID NO:9. It is well known that antisense sequences do not encode products related to the sense strand, for example, the 5'- 3' directionality is reversed, and therefore each codon triplets is read in the reverse orientation (encoding a different amino acid in most instances) and the N and C terminal of the encoded product is reversed. Applicant has not provided any guidance or working examples which would lead one of skill in the art to predict that the antisense strand of SEQ ID NO:9 (e.g. a nucleic acid which hybridizes to SEQ ID NO:9) does, in fact, encode protein product (e.g. start sequences, methionine codon, a substantial open reading frame, stop and other termination signals). Further, one of skill in the art would not predict that such a product would be structurally or functionally related to the protein with the sequence of SEQ ID NO:4, and applicant has not provided any potential means of using such an unrelated protein product, or any description of the structure or function of such a product.

With regard to claim 9, which encompasses transgenic animals, it is well known that genetic manipulation of transgenic animals is highly unpredictable (Sigmund, Arterioscler. Thromb. Vasc. Biol., 20:1425-1429, 2000; Bampton *et al.*, Brain Res., 841:123-134, 1999). Therefore, due to the lack of guidance in the art and the

specification, the use of host cells other than isolated host cells, grown *in vitro*, or transgenic plant cells, is not enabled.

Therefore, in view of the lack of support in the art and specification, it would require undue experimentation on the part of the skilled artisan to make and use the full scope of the claimed invention.

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 6, 8-10, 13, and 15 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

The term "high stringency conditions" in claim 6 is a relative term which renders the claim indefinite. The term " high stringency conditions " is not defined by the claim, the specification does not provide a standard for ascertaining the requisite degree, and one of ordinary skill in the art would not be reasonably apprised of the scope of the invention.

Claim Rejections - 35 USC § 102

> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 6, 8-10, 13, and 15 are rejected under 35 U.S.C. 102(b) as being anticipated by Altier *et al.* (WO 02/086072 A2, 2002; IDS filed 8/24/2006).

The instant claims are drawn to an isolated polynucleotide that comprises a sequence of nucleotides provided in SEQ ID NO:9, a sequence of nucleotides which is at least 66% identical to SEQ ID NO:9, or a sequence that hybridizes to either of these under high stringency conditions, as well as a vector comprising said polynucleotide and a host cell comprising said polynucleotide. The claims are also drawn to a transgenic plant that has been transformed with a polynucleotide that comprises a sequence of nucleotides provided in SEQ ID NO:9, a sequence of nucleotides which is at least 66%

identical to SEQ ID NO:9, or a sequence that hybridizes to either of these under high stringency conditions. Said transgenic plant must produce a peptide with an amino acid sequence as provided in SEQ ID NO:4, an amino acid sequence which is at least 60% identical to SEQ ID NO:4, a biologically active fragment of these, or a precursor comprising these sequences. Said peptide must exhibit antifungal and/or antibacterial activity.

Altier *et al.* disclose disease resistance-conferring DNA constructs for expression in plants (see page 38-39). These constructs comprise DNA with a sequence (SEQ ID NO:1 that has nucleotides 151-153 in common with nucleotides 37-39 of the instantly claimed SEQ ID NO:9) that encodes SEQ ID NO:2, which has amino acids 50-52 in common with amino acids 13-15 of the instantly claimed SEQ ID NO:4.

Conclusion

No claim is allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Brian J. Gangle whose telephone number is (571)272-1181. The examiner can normally be reached on M-F 7-3:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Robert Mondesi can be reached on 571-272-0956. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Brian J Gangle/
Examiner, Art Unit 1645

/Robert B Mondesi/
Supervisory Patent Examiner,
Art Unit 1645